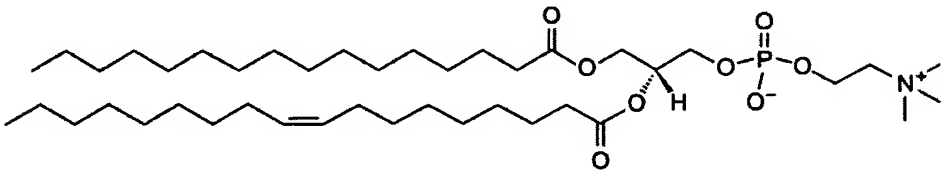
REMARKS

This application has been amended in manner that is believed to place the application in condition for allowance at the time of the next Official Action.

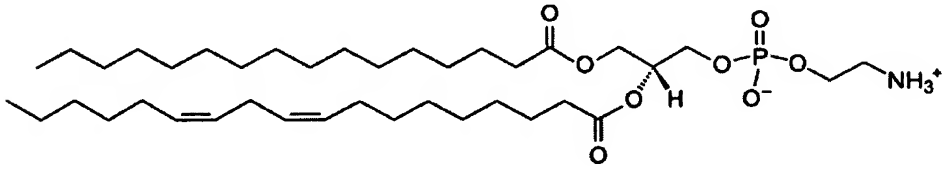
Claims 1-31 are pending in the application. Claims 1-28 have been amended to address the formal matters raised in the outstanding Official Action. Claims 29-31 have been added. Support for claims 29-31 may be found generally throughout the specification.

As to the election/restriction requirement, the Official Action contends that KIM et al. anticipate claim 1. KIM et al disclose polymers having a phosphate end group and a polyester chain. However, KIM does not disclose a phospholipid end group as claimed.

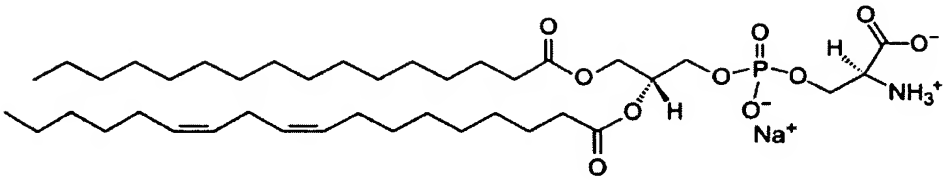
Examples of phospholipids are described below. These structures differ from KIM et al. in that the end group is polar and comprises amine.



Phospahatidyl choline.



Phospahatidyl ethanolamine



Phospahatidyl serine

A phospholipid group is not the equivalent to a phosphate group. If one replaced the polar phospholipid end group with a non-polar phosphate group, the polymer would not be amphiphilic and produce micelles or vesicles. A phosphate group would also not provide sufficient bioavailability for drug delivery.

The Official Action further states that there is no definition in the specification for the functional groups. However, the Exmainer' attention is respectfully directed to the present specification at page 8, paragraph 1, wherein terminal groups that are applicable to the polymer material are provided. The listing cites three phospholipid groups, i.e. phosphatidyl choline, phosphatidyl ethanolamine, phosphatidyl serine. The rest of the groups that are listed are not phospholipids but groups that may be combined with phospholipid products.

From page 8, paragraph 3 to the end of the specification, the present specification describes in detail a method for producing the polymers and even exemplifies a polymer with such a phosphatidyl choline group. The reaction scheme in Figure 1 (see end product 3) also describes the method and

polymer based on a phospholipid (e.g., phosphatidyl choline). Therefore, it is believe that one skilled in the art is given sufficient guidance to practice the invention.

The Official Action also contends that the burden in searching for the claimed invention would be undue since these phospholipids can vary. However, in view of the above, it is believed to be apparent that the search should be directed to biodegradable polyesters having phospholipid end groups and is not undue.

Applicants also note that the Official Action does not provide any evidence that a polyester combined with a phospholipid is known. Thus, the present invention is not anticipated by KIM et al.

In this regard, it is believed that the Official Action fails to satisfy its burden in showing the claimed invention lacks a special technical feature and respectfully request a search and examination of all of the claims in their full scope.

Claims 1-7 and 10-12 were rejected under 35 USC §112, second paragraph, for allegedly being indefinite. This rejection is traversed.

The phrase "terminal functional group based on hydrophilic moieties of phospholipids" is explained in the specification on page 8, lines 3-8, "The terminal group is selected from but not restricted to phosphatidyl choline, phosphatidyl ethanolamine, phosphatidyl serine". Thus, the terms

phospholipids, phosphatidyl ethanolamine, phosphatidyl serine and phosphatidyl choline are known to a person skilled in the art. Enclosed are examples from text books explaining these terms (Horton, Moran, Oschs, Rawn and Scrimgeour, Principles of Biochemistry, 2nd Edition, Prentice-Hall International, Inc. p262; and Stryer, Biochemistry, 4th Edition, W. H. Freeman and Company, New York, p268).

Natural phospholipids contain a variety of functional groups in their polar head groups. A common theme is the phosphate esters. These groups are combined with other functional groups such as ammonium (phosphatidyl choline, PC), carboxylic acid or carboxylate (phosphatidyl serine), carbohydrates such as inositol (phosphatidyl inositol) and so on to form different species, all being part of the hydrophilic part of phospholipids. Introduction of the PC group is described in paragraphs 2 and 3 on page 8. The introduction of cationic groups is described beginning on page 8, paragraph 4. The introduction of the anionic groups is described on page 9, paragraphs 2 and 3. Thus, the combination of the polar heads of phospholipids and other functional groups is definite (Ishizuka, Prog. Lip. Res., 36(4), p. 245-319, 1997; Lindh and Stawinski, J. Org. Chem., 54, p. 1338-1342, 1989; Ferguson, Homan, Dwek and Rademacher, Science, 4841(239), p. 753-759, 1988).

Thus, applicants respectfully request that the rejection be withdrawn.

Claims 1, 4-7 and 10-11 were rejected under 35 USC §102(a) as allegedly being anticipated by LUCKE et al. This rejection is traversed.

LUCKE et al. studied the influence of acylformation during degradation of certain polyesters and possible protein/peptide degradation caused by acylation. LUCKE et al. have observed that poly(lactic acid) and copolymers with glycolic acid (poly(lactic-co-glycolic acid)) degrade and form acyl groups when subjected to moisture.

LUCKE et al. also studies how these acyl groups might affect an eventual encapsulated protein/peptide. LUCKE et al. have not studied, disclosed or mentioned polymers with functional groups of phospholipid moieties or biodegradable polymers with ionic functional groups.

Thus, LUCKE et al. do not anticipate the claimed invention.

Claims 2 and 12 were rejected under 35 U.S.C. 102(b) as allegedly being anticipated by HECHT. This rejection is traversed.

In imposing the rejection, the Official Action contends that "coumarin"-terminated materials studied by HECHT et al. could be encompassed in the term "phospholipid moieties". Coumarin is a substance found in perfumes. There are no known natural phospholipid structures that contain a coumarin skeleton. According to Figure 1 below, coumarin could not be a

"phospholipid moiety" since, as explained above, it does not involve functional groups derived from phosphate end groups.

According to the present invention, the terminal functional group preferably comprise one or more charged groups, page 8; lines 1-2. The "coumarin"-terminated materials studied by HECHT et al. do not carry any charges.

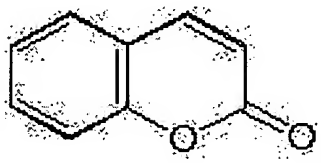


Figure 1. Coumarin.

Thus, HECHT does not anticipate the claimed invention.

Claim 3 was rejected under 35 USC §102(b) as allegedly being anticipated by BURT et al. This rejection is traversed.

The Official Action states that "methoxypolyethylene glycol" (molecular formula $CH_3O(CH_2CH_2O)_nH$) studied by BURT et al. could be encompassed in the term "phospholipid moieties". However, since "phospholipid moieties", as explained above, involves functional groups derived from a combination of the polar head of phospholipids and other functional groups, methoxypolyethylene glycol can not be encompassed in the term phospholipid moiety.

In view of the above, applicants respectfully submit that the publications fails to disclose or suggest the claimed invention.

Claim 2 was rejected under 35 USC §103(a) as allegedly being unpatentable over the WO 00/56802 publication. This rejection is traversed.

WO 00/56802 describes hyperbranched polymer structures based on non-degradable polyether linkages. Further post-functionalization with lactones add linear degradable polyester fragments (page 9, 1st paragraph). Non-degradable polymers (that do not undergo biodegradation) are not implied or used in the present invention since these are not desirable for the targeted application, drug-delivery systems and WO 00/56802 does not disclose or suggest the claimed polymer having a core as recited.

Claim 18 was rejected under 35 USC §103(a) as allegedly being unpatentable over U.S. Patent 6,166,173 in view of KIM et al. This rejection is traversed.

U.S. Patent No. 6,166,173 ("'173") describes synthetic methods to incorporate phosphates into the polymer backbone. The syntheses follow principles of step-growth polymerization resulting in polymers where the number and distribution of phosphates in the backbone is highly varied and uncertain. This stands in contrast to the present invention. The present invention describes how the end groups of these polymers can be functionalized with phosphates. The number of end groups can be varied as a result of the desired architecture. Additionally, unlike pendant groups along the main chain, functional end groups can, especially if they are ionic, form micelles or particles,

these can be used as vesicles for drugs, genes or growth factors in therapeutic treatments.

Moreover, '173 does not describe phospholipid end groups as claimed.

KIM describes ring-opening polymerization starting from an already synthesized phosphotriester initiator carrying an alcohol functionality. This results in a polymer where only one end group is functionalized. The phosphate is not charged and it is introduced prior to polymerization.

However, the present invention is directed to polymerization and post-functionalization resulting in the control of the introduction of a selected number of functional groups depending on the desired polymer architecture, e.g. linear, dendritic. Unlike KIM, where the number of phosphate functional groups is limited to only one, the present invention facilitates multiple functionalizations since each alcohol can be converted into a phospholipid moiety.

Moreover, the functional group that is introduced according to present invention is charged, it is either a cat-, an- or zwitterions, giving an amphiphilic material. An amphiphilic material can form micelles or membranes to encapsulate drugs, proteins, growth factors etc. The material according to KIM would not be useful for micelles or membranes since the functional end group is not polar enough and would not

therefore separate into a hydrophilic and a hydrophobic phase. Moreover, KIM does not describe phospholipid end groups.

'173 provides a synthetic route of synthesising biodegradable polymers containing phosphate linkages of various kinds. The polymers in document '173 are meant for in vivo applications, i.e. biomaterials and drug delivery systems. However, these polymers are not amphiphilic (they do not have a hydrophobic and a hydrophilic part) due to the fact that phosphate groups are evenly distributed along the main chain. A non-amphiphilic polymer would therefore only collapse into polymeric bundles. Additionally, document '173 does not provide a way to synthesise dendritic structures.

'173 also fails to mention or describe micelles, vesicles or dendritic structures, and there is no mention of a desire to produce such polymeric structures or any methods of producing such.

While KIM presents a way of synthesising biodegradable initiators containing phosphate end groups, the phosphate end groups are not of ionic structure and a person skilled in the art would realise that the hydrophilicity of the phosphate group would not be enough to create micelles.

Moreover, KIM discloses a synthetic route for low molecular weight polymers (M_n ~5000g/mol) as initiators. '173 does not disclose a use for any of the products that are produced.

As noted above, the present invention is directed to a a fully biodegradable polymer, whereas the polymer presented in KIM is only partly biodegradable (the initiator), the rest is non-biodegradable (poly(glycidyl phenyl ether.

Thus, applicants submit that the proposed combination of publication would not results in the claimed invention for the reasons noted above.

Indeed, even if a person skilled in the art would combine these two publications, the final polymer would have only one phosphate group (according to KIM). The present invention presents a way of incorporating multiple end groups and dendritic structures (see page 5, line 7; and page 8, lines 1-2).

In addition, none of these functional groups are hydrophilic enough or carrying any ionic groups to facilitate micelle formation.

The person skilled in the art would thus not arrive at the claimed invention even by chance. In view of the above, applicants respectfully request that the obviousness rejections be withdrawn.

Applicants note with appreciation the indication that claims 19-20 are objected to as being dependent upon a rejected based claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

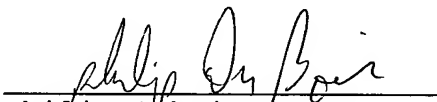
In view of the present amendment and foregoing remarks, therefore, applicants believe that the present application is in condition for allowance at the time of the next Official Action. Allowance and passage to issue on that basis is respectfully requested.

Please charge the fee of $75 for the three extra claims of any type added herewith, to our credit card as set forth on the attached Credit Card Payment Form.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

YOUNG & THOMPSON



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